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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/671,270

09/24/2003

Peter A. Altman

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3869

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EXAMINER

CHENG, JACQUELINE

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

09/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/671,270

Applicant(s)

ALTMAN ET AL.

Examiner

Jacqueline Cheng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claim 1-41 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1-6, 11-16, 21-26, and 31-36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry (US 5,439,446) further in view of Stevens (US 6,152,141). Barry discloses an apparatus for treating irregularities in a vessel of a patient such as a stenosis (col. 4 line 27-32). The apparatus comprises of a stent and administration of therapeutic agents to reduce the risk of restenosis (col. 3 line 38-57). Stents are used in many applications such as in angioplasty procedures (col. 11-18). As shown in figures 2 Barry discloses a catheter (element 30) with a distal end that supports an expansible balloon (element 35) with an expandable stent (element 36). The catheter also has a port (element 42) positioned proximal to the balloon, connected to a therapeutic agent source to inject a anti-restenosis agent such as gene therapy agents into the volume (col. 6 line 21-32, col. 60-68, col. 7 line 1-8). What Barry does not explicitly disclose is use of this stent and therapeutic agent in the coronary blood vessel and in

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the myocardium. Stevens discloses a method of delivery of therapeutic agents to the heart. Steven also discloses a catheter with a delivery port to deliver a therapeutic agent to the myocardium. He discloses that another agent delivery technique besides the delivery port is to inject the agent directly into the myocardium (col. 8 line 21-40). It would be obvious to combine the apparatus of Barry with the method of Stevens to place the apparatus of Barry (of the catheter, stent, and delivery of therapeutic agent) within the coronary blood vessel as the apparatus of Barry can be used in any vessel. Stevens shows that it is well known in the art to, instead of using a delivery port, one can use a needle to inject a therapeutic agent (such as an anti-stenosis agent) into the myocardium. The stent can be placed in the endocardial or peri-adventitial area, which would mean the therapeutic agent will be injected into the myocardium from these areas. Also the needle can be placed anywhere, such as at a site distal to the stent.

4. **Claims 7-9, 17-19, 27-29 and 37-39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Stevens further in view of Mixson (US 6,090,728). Mixson discloses carrier vehicles for an anti-angiogenic agents comprising micelles and microspheres.

5. **Claims 10, 20, 30 and 40** are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Stevens further in view of Rossi (US 6,379,931 B1). Rossi discloses that therapeutic agents for inhibiting stent induced restenosis can be injected with encapsulated liposomes (col. 6 line 63-67).

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6. **Claim 41** is rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens further in view of Kunz (US 5,981,568). Neither Barry nor Stevens explicitly disclose a kit comprising the parts of their method. It would be obvious to put the parts needed to perform a method in a kit as well as instructions to perform the method as this is well known in the art to do. For example, Kunz discloses not only a kit to perform a method, but also discloses in particular a kit for inhibiting restenosis comprising a catheter, a dose of therapeutic agent, and instruction means for directing the kit's use. Since the method of Stevens comprises positioning the catheter into the desired location (capable of being the perivasular space) and delivering the dose to where the catheter is placed, it would be obvious that the instructions would state this.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596.

The examiner can normally be reached on M-F 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC


ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER